

NOV 29 2000

K001278

**510(k) SUMMARY**  
**of**  
**SAFETY and EFFECTIVENESS**

**A. General Information**

1. *Manufacturer:* QRS Diagnostic, LLC
2. *Address:* 14755 27<sup>th</sup> Avenue No.  
Plymouth MN, 55447
3. *Telephone:* 763-559-8492, Ext. 947
4. *Contact Person:* David Lerner
5. *Date Prepared:* April 17, 2000
6. *Registration Number:* 2133542

**B. Device**

1. *Name:* Sensaire® Handheld Diagnostic Spirometer
2. *Trade Name* Sensaire® Diagnostic Spirometer
3. *Common Name:* Diagnostic Spirometer
4. *Classification:* Spirometer, Diagnostic
5. *Product Code:* BZG
6. *Class:* Class II
7. *Regulation Number:* 868.1840

**C. Identification of Legally Marketed Devices**

1. *Name:* SpiroCard
2. *K Number:* K973138
3. *Date Cleared:* October 28, 1998

**D. Description of the Device**

The Sensaire® is a low cost, full-featured spirometer designed to address the needs of healthcare practitioners who desire portability. The device's target list price is under \$1,000 which provides a more affordable solution for primary care physicians who are hesitant to purchase competitive devices costing twice as much. The Sensaire's main feature will be its backlit, LCD touchscreen, allowing real-time graphical display and review of the spirometry loop along with alpha character patient entry when desired. The Sensaire's second most beneficial feature will be its precalibrated, biodegradable disposable mouthpieces, which can minimize the risk of cross-contamination when changed for every patient and can also allow users to be mobile without the need for carrying a 3-liter syringe. Additional features will be the rechargeable battery pack and its serial data output directly to a printer for reporting purposes.

Most users will utilize only the Forced Vital Capacity (FVC) spirometry test; however, all screening spirometry tests will be available, including pre/post bronchodilator testing, Maximum Voluntary Ventilation (MVV), and Slow Vital Capacity (SVC).

**E. Intended Use Statement**

Diagnostic Spirometry

*Spirometric Maneuvers:* FVC, SVC, MVV

*Patient Population:* Male/Female, Pediatric to Adult

*Environment of Use:* Hospital, Clinic and Home Use

**F. Components**

- Handheld unit
- Disposable biodegradable mouthpieces
- Base station
- AC Adapter
- Stylus
- Communication cable
- Battery pack

- Serial to parallel converter for printing

## G. Summary Table of Comparisons

The following summary tables of comparisons compare the new device (Sensaire) to the predicate device (SpiroCard).

### Product Description

#	Area	New Device: Sensaire	Predicate Device: SpiroCard	Same	Different
1	System Components	Spirometer Mouthpieces Power cord Charging unit	Spirometer Mouthpieces Power cord Hand Held PC Pressure Tube		X
2	Disposable Accessories	Mouthpieces (2)	Mouthpieces (2)	X	
3	Computer Required for use	None required	Hand Held PC		X
4	Weight	Hand Held 14 oz. Base Station 6 oz.	PC Card 1.6 oz.		X
5	Dimensions	Handheld: 7 x 3 x 2 inches  Base Station: 5 x 4 x 2 inches	PC Card: 6 x 2 x ½ inches		X
6	Off-the-Shelf Software required for use	None required	Windows CE		X
7	Dedicated unit	Yes. The Sensaire only performs spirometry.	Yes. The SpiroCard only performs spirometry.	X	

### Product Labeling

#	Area	New Device: Sensaire	Predicate Device: SpiroCard	Same	Different
1	Indications for use	Diagnostic Spirometry: FVC MVV SVC FEF	Diagnostic Spirometry: FVC MVV SVC FEF	X	
2	Target population	Male/Female Pediatric to Adult	Male/Female Pediatric to Adult	X	

#	Area	New Device: Sensaire	Predicate Device: SpiroCard	Same	Different
3	Sterility	Non-Sterile	Non-Sterile	X	
4	Prescription Required?	Yes	Yes	X	
5	Where used: hospital, home, ambulance, etc.	Hospital, Clinical and Home Use	Hospital, Clinical and Home Use	X	
6	Ambient Temperature	17C to 40C	15C to 35C		X
7	Operating Humidity	30% to 75%	Not more than 90%		X
8	Performance Standards	Complies with American Thoracic Society (ATS) Standardization of Spirometry, 1994 Update	Complies with American Thoracic Society (ATS) Standardization of Spirometry, 1994 Update	X	
9	Safety Standards	Complies with EN60601-1 UL 2601-1 IEC60601-1	Complies with EN60601-1 UL 2601-1 IEC60601-1	X	

### Product Design

#	Area	New Device: Sensaire	Predicate Device: SpiroCard	Same	Different
1	QRS Software	Flash Memory Driver Software	Reporting Software Driver Software		X
2	Calibration Self- Check	Yes	Yes	X	
3	Predicted Normals	Knutson	Knutson Cherniack Roberts Crapo Warwick Polgar Morris HSU		X

#	Area	New Device: Sensaire	Predicate Device: SpiroCard	Same	Different
4	Parameters Measured	FVC FEV1 PEFR FEF25-75% MVV MTV SVC	FVC FEV0.5 FEV1 FEV1/FVC FEV3 FEV3/FVC PEFR FEF25% FEF50% FEF75% FEF25%-75% FIVC FIV0.5 FIV1 FIV1/FIVC FIV3 FIV3/FIVC PIFR FIF50% FIF 25-75% FIF2-1.2 FVC/FIVC PIFR PEFR/PIFR Ext. Vol. MVV RR MTV SVC		X
5	Sampling Rate	100 Samples per Second	100 Samples per Second	X	
6	Printed Scale Volume/Time	Volume: 10mm/L Time: 1 cm/s	Volume: 10mm/L Time: 1 cm/s	X	
7	Printed Scale Flow/Volume	Flow: 5 mm/L/sec minimum Volume: 10mm/L	Flow: 5 mm/L/sec minimum Volume: 10mm/L	X	
8	Measuring Time	Up to 30 sec.	Up to 30 sec.	X	
9	Resistance to Shock	Tested per IEC 60068- 2-27. Meets performance requirements.	Tested per IEC 60068- 2-27. Meets performance requirements.	X	
10	Resistance to Random and Sinusoidal Vibration	Tested per IEC 60068- 2-6 and IEC 60068-2- 34. Meets performance requirements.	Tested per IEC 60068- 2-6 and IEC 60068-2- 34. Meets performance requirements.	X	
11	Operating Conditions: Temperature and Humidity	Meets requirements of Labeling for Recommended Operating Conditions	Meets requirements of Labeling for Recommended Operating Conditions	X	

### Product Safety

#	Area	New Device: Sensaire	Predicate Device: SpiroCard	Same	Different
1	Mouthpiece Material	Paper Art-board	Plastic		X
2	Mechanical safety	Complies with EN60601-1-1	Complies with EN60601-1-1	X	
3	Energy used and/or delivered	Energy delivered: None. Energy used: Electrical and Battery	Energy delivered: None. Energy used: Electrical and Battery	X	
4	Power Supply	Provided with unit.	Provided by Hand Held Computer		X
5	Compatibility with environment and other devices	Complies with EN60601-1-2 and EN55011	Complies with EN60601-1-2 and EN55011	X	
6	Radiation safety	Complies with EN60601-1	Complies with EN60601-1	X	
7	Electrical safety	Complies with EN60601-1	Complies with EN60601-1	X	

### Product Efficacy

#	Area	New Device: Sensaire	Predicate Device: SpiroCard	Same	Different
1	Method of Operation	Spirometric test conducted per ATS	Spirometric test conducted per ATS	X	
2	Anatomical sites	Patient is required to exhale and inhale in to the mouthpiece	Patient is required to exhale and inhale in to the mouthpiece	X	
3	Human factors	Portable	Portable	X	
4	Performance Standard	Complies with American Thoracic Society (ATS) Standardization of Spirometry, 1994 Update	Complies with American Thoracic Society (ATS) Standardization of Spirometry, 1994 Update	X	
5	ATS Accuracy	Flow: $\pm 5\%$ of indication or $\pm 200\text{ml/s}$ , whichever is greater for FEF25-75% and $\pm 10\%$ of indication or $\pm 400\text{ml/s}$ , whichever is greater for PEF  Volume: $\pm 3\%$ of	Flow: $\pm 5\%$ of indication or $\pm 200\text{ml/s}$ , whichever is greater for FEF25-75% and $\pm 10\%$ of indication or $\pm 400\text{ml/s}$ , whichever is greater for PEF  Volume: $\pm 3\%$ of	X	

#	Area	New Device: Sensaire	Predicate Device: SpiroCard	Same	Different
		indication or $\pm 50\text{ml}$ , whichever is greater for FVC and FEV1	indication or $\pm 50\text{ml}$ , whichever is greater for FVC and FEV1		
6	ATS Precision	Flow: $\pm 5\%$ of indication or $\pm 200\text{ml/s}$ , whichever is greater for FEF25-75% and $\pm 5\%$ of indication or $\pm 200\text{ml/s}$ , whichever is greater for PEF  Volume: $\pm 3\%$ of indication or $\pm 50\text{ml}$ , whichever is greater for FVC and FEV1	Flow: $\pm 5\%$ of indication or $\pm 200\text{ml/s}$ , whichever is greater for FEF25-75% and $\pm 5\%$ of indication or $\pm 200\text{ml/s}$ , whichever is greater for PEF  Volume: $\pm 3\%$ of indication or $\pm 50\text{ml}$ , whichever is greater for FVC and FEV1	X	
7	Range of Operation: Flow	-14 to + 14 liters per second	-14 to + 14 liters per second	X	
8	Range of Operation: Volume	0 to 8 liters BTPS	0 to 8 liters BTPS	X	
9	BTPS Correction per American Thoracic Society (ATS) Standardization of Spirometry, 1994 Update	Yes	Yes	X	

#### **D. Discussion of Similarities and Differences**

The Sensaire and SpiroCard have the following similarities or are the same according to the previous comparison tables.

- Disposable accessories
- Dedicated unit
- Indications for use
- Target population
- Prescription required
- Sterility
- Where used
- Performance standards
- Safety standards
- Volume measurement method
- Flow measurement method
- Calibration self-check
- Sampling rate
- Printed scale: Volume/Time
- Printed scale: Flow/Volume
- Measuring time
- Resistance to shock
- Resistance to random and sinusoidal vibration
- Operating conditions: temperature and humidity
- Mechanical safety
- Energy used and/or delivered
- Compatibility with environment and other devices
- Radiation safety
- Electrical safety
- Method of operation
- Anatomical sites
- Human factors
- Performance standard
- ATS accuracy
- ATS precision
- Range of operation: flow
- Range of operation: volume
- BTPS correction

The differences, with comments, are the following:

- System Components – Sensaire has fewer components than SpiroCard, none of which affects testing, accuracy or precision.
- Computer Required for Use – Sensaire does not require a computer for use, whereas the SpiroCard requires a handheld PC.
- Weight – Obviously, the PC card of the SpiroCard weighs less than the total unit of the Sensaire.
- Dimensions – The Sensaire is larger, but remember, it has fewer components and it has not affected accuracy, testing or precision.
- Off-the-Shelf (OTS) Software Required – The SpiroCard requires Window CE to operate, while the Sensaire has no OTS software.
- Operating Conditions: Ambient Temperature – The ranges of ambient temperature operating conditions are just a little different due to the touchscreen on the Sensaire.
- Operating Conditions: Humidity – The humidity levels for the Sensaire are somewhat tighter, again due to the touchscreen.
- QRS Software – The Sensaire has flash memory versus reporting software.
- Predicted Normals – The Sensaire utilizes Knutson's predictors, whereas the SpiroCard has the capability to use Knutson and others.
- Parameters Measured – The Sensaire measures seven basic parameters; the SpiroCard has the capability to measure additional parameters.
- Actual Resolution – The resolution for the Sensaire is 3 ml/s versus 1 ml/s for the SpiroCard, both of which are far lower than the ATS requirements.
- Mouthpiece Material – The SpiroCard mouthpiece is plastic versus paper for the Sensaire.
- Power Supply – The Sensaire is powered by rechargeable batteries that can be docked in the base station.

The above differences do not raise any new types of safety or effectiveness questions.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 29 2000

Mr. David Lerner  
QRS Diagnostic, LLC  
14755 27<sup>th</sup> Avenue N.  
Plymouth, MN 55447

Re: K001278  
Sensaire® Handheld Diagnostic Spirometer  
Regulatory Class: II (two)  
Product Code: 73 BZG  
Dated: September 12, 2000  
Received: September 14, 2000

Dear Mr. Lerner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

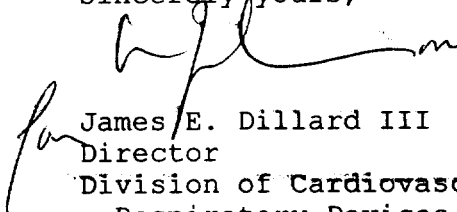
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. David Lerner

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



James E. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number: K001278

Device Name: Sensaire® Diagnostic Spirometer

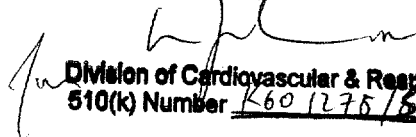
**Indications for Use:**

- Diagnostic Spirometer
  - Patient Population: Male/Female, Pediatric to Adult
  - Device Functionality: Diagnostic Spirometer
  - Spirometric Parameters: FVC, SVC and MVV
  - Environment of Use: Hospital, Clinic and Home
  - Prescription Device by a Physician

PLEASE DO NOT WRITE BELOW THIS LINE –  
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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K601275/51

Prescription Use ☒

OR

OVER-THE-COUNTER USE ☐  
(optional Form 1-2-96)